

(12) PATENT
(19) AUSTRALIAN PATENT OFFICE

(11) Application No. AU 199895079 B2
(10) Patent No. 739429

(54) Title
Contraceptive transcervical falloplan tube occlusion devices and methods

(51)⁷ International Patent Classification(s)
A61F 006/06

(21) Application No: **199895079**

(22) Application Date: **1998.09.23**

(87) WIPO No: **WO99/15116**

(30) Priority Data

(31) Number	(32) Date	(33) Country
60/059861	1997.09.24	US
09/093835	1998.06.08	US

(43) Publication Date : **1999.04.12**

(43) Publication Journal Date : **1999.06.10**

(44) Accepted Journal Date : **2001.10.11**

(71) Applicant(s)
Conceptus, Inc.

(72) Inventor(s)
Julian N. Nikolchev; Dai T. Ton; Ashish Khara; Donnell W. Gurskls; Steven Bacich

(74) Agent/Attorney
SPRUSON and FERGUSON, GPO Box 3898, SYDNEY NSW 2001

(56) Related Art
EP 105669
WO 96/40024
WO 80/82369

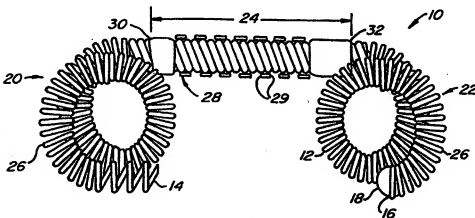


AU9895079

INT

<p>(51) International Patent Classification ⁶ : A61F 6/06</p>	<p>A1</p>	<p>(11) International Publication Number: WO 99/15116 (43) International Publication Date: 1 April 1999 (01.04.99)</p>
<p>(21) International Application Number: PCT/US98/20031 (22) International Filing Date: 23 September 1998 (23.09.98) (30) Priority Data: 60/059,861 24 September 1997 (24.09.97) US 09/093,835 8 June 1998 (08.06.98) US (63) Related by Continuation (CON) or Continuation-in-Part (CIP) to Earlier Applications US 60/059,861 (CIP) Filed on 24 September 1997 (24.09.97) US 09/093,835 (CIP) Filed on 8 June 1998 (08.06.98) (71) Applicant (for all designated States except US): CONCEPTUS, INC. [US/US]; 1021 Howard Avenue, San Carlos, CA 94070 (US). (72) Inventors; and (75) Inventors/Applicants (for US only): NIKOLCHEV, Julian, N. [US/US]; 251 Duranzo Way, Portola Valley, CA 94028 (US). TON, Dai, T. [US/US]; 1693 Flickinger Avenue, San Jose, CA 95131 (US). KHERA, Ashish [US/US]; 1630 Sanchez Street #3, San Francisco, CA 94131 (US).</p>		<p>GURSKIS, Donnell, W. [US/US]; 3251 Anastacia Court, Pleasanton, CA 94588 (US). BACICH, Steven [US/US]; 20 Fairway Place, Half Moon Bay, CA 94019 (US). (74) Agents: BARRISH, Mark, D. et al.; Townsend and Townsend and Crew LLP, 8th floor, Two Embarcadero Center, San Francisco, CA 94111 (US). (81) Designated States: AU, CA, JP, US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report. Before the expiration of the time limits for amending the claims and to be republished in the event of the receipt of amendments.</i></p>

(54) Title: CONTRACEPTIVE TRANSCERVICAL FALLOPIAN TUBE OCCLUSION DEVICES AND METHODS



(57) Abstract

The invention provides intrafallopian devices and non-surgical methods for their placement to prevent conception. The efficacy of the device (10) is enhanced by forming the structure at least in part from copper or a copper alloy. The device (10) is anchored within the fallopian tube by a lumen-traversing region of the resilient structure which has a helical outer surface, together with a portion of the resilient structure which is biased to form a bent secondary shape, the secondary shape having a larger cross section than the fallopian tube. The resilient structure is restrained in a straight configuration and transcervically inserted within the fallopian tube, where it is released. Optionally, permanent sterilization is effected by passing a current through the resilient structure to the tubal walls.

5

CONTRACEPTIVE TRANSCERVICAL FALLOPIAN TUBE OCCLUSION DEVICES AND METHODS

10

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of U.S. Patent Application Serial No. 09/093,835, filed June 8, 1998, which is a continuation of U.S. Provisional Application No. 60/059,861, filed September 24, 1997, the full disclosures of which are incorporated herein by reference.

15

BACKGROUND OF THE INVENTION

20

1. Field of the Invention

The present invention relates generally to contraception, and more particularly to intrafallopian contraceptive devices and nonsurgical methods for their delivery.

Worldwide demand exists for safe, effective methods of both contraception and permanent sterilization. Although a variety of contraception and sterilization methods are available, all of the existing methods have limitations and disadvantages. Thus, the need for additional safe, low cost, reliable methods of contraception and permanent sterilization, both in developed and less developed countries, is widely recognized.

25

30

Many presently available contraception methods require significant user involvement, and user non-compliance results in quite high rates of failure. While the theoretical effectiveness of existing contraceptives, including barrier methods and hormonal therapies, is well established, overcoming user noncompliance to improve overall efficacy has proven difficult.

35

One form of contraception which is less susceptible to user noncompliance is the intrauterine device (IUD). IUDs have been found to have higher rates of reliability, and are effective for a longer period of time, than most other commercially available contraceptives. Unfortunately, IUDs are also associated with serious infectious complications. For this reason, the use of IUDs within the United States has decreased dramatically. Additionally, IUDs are subject to unplanned expulsion, and must be removed due to excessive pain or bleeding in a percentage of cases, further reducing the acceptance of the IUD as a contraceptive method. Interestingly, the efficacy of copper IUDs appears to be higher than that of non-metallic IUDs. The reason for this has not been fully explained.

Commercially available options for permanent sterilization include fallopian tube ligation and vasectomy. These methods are surgical, are difficult to reverse, and are not available to many people in the world. It is common knowledge that fertilization occurs in the fallopian tubes where the sperm and ovum meet. Tubal ligation avoids this by complete occlusion of the fallopian tubes.

It has previously been proposed to reversibly occlude the fallopian tubes, for example, by *in vitro* formation of an elastomeric plug, or otherwise anchoring a device on either side of the narrowest region of fallopian tube, called the "isthmus." Such fallopian tube occlusion methods appear promising; however, an unacceptably high percentage of the non-surgical devices proposed to date have become dislodged during previous studies. Even where non-surgical intrafallopian devices have remained in place, they have been found to be only moderately effective at preventing conception.

For these reasons, it would be desirable to provide effective, reliable intrafallopian devices for contraception and sterilization. It would be particularly desirable to provide highly effective intrafallopian devices which did not require surgery for placement. It would be especially desirable if such devices and methods allowed easy placement

of the device, but were less susceptible to being dislodged than previously proposed non-surgical intrafallopian devices.

5 2. Description of the Related Art

 The experimental use of a stainless steel intrafallopian device is described in *Transcatheter Tubal Sterilization in Rabbits*, Penny L. Ross, RT 29 "Investigative Radiology", pp. 570-573 (1994). The experimental use of an electrolytically pure copper wire as a surgical contraceptive intrafallopian device in rats was described in "Antifertility Effect of an Intrafallopian Tubal Copper Device", D.N. Gupta, 14 *Indian Journal of Experimental Biology*, pp. 316-319 (May 1976).

 U.K. Patent Application Pub. No. 2,211,095 describes a uterine screw plug for blocking the fallopian tube. European Patent Application Pub. No. 0,010,812 describes a device for placement in the oviducts having enlargements at either end for anchoring the device. The same device appears to be described in Netherlands Patent No. 7,810,696.

 The use of tubal occlusion devices is described in "Hysteroscopic Oviduct Blocking With Formed-in-Place Silicone Rubber Plugs", Robert A. Erb, Ph.D., et al., *The Journal of Reproductive Medicine*, pp. 65-68 (August 1979). A formed-in-place elastomeric tubal occlusion device is described in U.S. Patent No. 3,805,767, issued to Erb. U.S. Patent No. 5,065,751, issued to Wolf, describes a method and apparatus for reversibly occluding a biological tube. U.S. Patent No. 4,612,924, issued to Cimber, describes an intrauterine contraceptive device which seals the mouths of the fallopian tubes.

 German Patent No. 28 03 685, issued to Brundin, describes a device for plugging a body duct with a device which swells when in contact with a body fluid.

 Alternative contraceptive devices are disclosed in co-pending U.S. Patent Application No. 08/474,779, the full disclosure of which is herein incorporated by reference.

SUMMARY OF THE INVENTION

Accordingly, in a first aspect, the present invention provides a contraceptive device for use in a fallopian tube having a tubal wall, the contraceptive device
5 comprising:

a tubular retention structure having a proximal end, a distal end, and an axis therebetween and a radially expandable structure disposed about said axis, the retention structure is radially expandable in situ from a narrow configuration to an expanded configuration, the retention structure in the narrow configuration having a first diameter
10 suitable for axial insertion into the fallopian tube, and in the expanded configuration having a second diameter larger than the first diameter and adapted to engage the surrounding tubal wall and retain the contraceptive device within the fallopian tube while a portion of the fallopian tube remains open around or through the retention structure.

6
5
4
3
2
1
10
9
8
7
6
5
4
3
2
1



In a second aspect, the present invention provides a contraceptive method comprising:

transcervically inserting an intrafallopian contraceptive device, having a straight
5 primary coil and a radially expandable structure disposed around said coil, along a fallopian tube by guiding the contraceptive device with a distal guidewire-like structure of the contraceptive device; and

retaining the device, including at least a portion of the guidewire-like structure,
within the fallopian tube by expanding said radially expandable structure so that the
10 device inhibits conception.



In a preferred embodiment, the use of copper improves the efficacy of the device as a contraceptive method. Devices formed from plastically deformable materials, however, are less readily restrained in the fallopian tube. Apparently, the large variation
5 in the actual shape and dimensions of the fallopian tubes does not provide reliable anchoring for a pre-formed deformable intrafallopian device. The preferred embodiment, therefore often comprises a resilient structure, usually a metallic coil, which includes a copper alloy or plating, ideally comprising an alloy including at least 75% copper. The coil material typically includes beryllium, zinc, stainless steel, platinum, a shape memory
10 alloy, such as Nitinol®, or the like. Preferably, the coil is composed of an alloy of beryllium and copper.

500

500



Although the preferred embodiment will generally result in occlusion, it need not completely occlude the fallopian tube to prevent the meeting of the sperm and ovum. Instead, in some embodiments, the presence of the copper on the resilient structure is
5 sufficient to provide effective contraception. Hence, contraception can be provided by disrupting the normal architecture and/or functional of the fallopian tube, despite the presence of an open lumen. This concept is referred to herein as "functional occlusion". As used herein, functional occlusion means that the device, when implanted in the fallopian tube, disrupts the normal architecture and/or functioning of the fallopian tube so
10 as to inhibit fertilization and/or conception.

P
5
10
15
20
25
30
35
40
45
50
55
60
65
70
75
80
85
90
95
100
105
110
115
120
125
130
135
140
145
150
155
160
165
170
175
180
185
190
195
200
205
210
215
220
225
230
235
240
245
250
255
260
265
270
275
280
285
290
295
300
305
310
315
320
325
330
335
340
345
350
355
360
365
370
375
380
385
390
395
400
405
410
415
420
425
430
435
440
445
450
455
460
465
470
475
480
485
490
495
500
505
510
515
520
525
530
535
540
545
550
555
560
565
570
575
580
585
590
595
600
605
610
615
620
625
630
635
640
645
650
655
660
665
670
675
680
685
690
695
700
705
710
715
720
725
730
735
740
745
750
755
760
765
770
775
780
785
790
795
800
805
810
815
820
825
830
835
840
845
850
855
860
865
870
875
880
885
890
895
900
905
910
915
920
925
930
935
940
945
950
955
960
965
970
975
980
985
990
995P
5
10
15
20
25
30
35
40
45
50
55
60
65
70
75
80
85
90
95
100
105
110
115
120
125
130
135
140
145
150
155
160
165
170
175
180
185
190
195
200
205
210
215
220
225
230
235
240
245
250
255
260
265
270
275
280
285
290
295
300
305
310
315
320
325
330
335
340
345
350
355
360
365
370
375
380
385
390
395
400
405
410
415
420
425
430
435
440
445
450
455
460
465
470
475
480
485
490
495
500
505
510
515
520
525
530
535
540
545
550
555
560
565
570
575
580
585
590
595
600
605
610
615
620
625
630
635
640
645
650
655
660
665
670
675
680
685
690
695
700
705
710
715
720
725
730
735
740
745
750
755
760
765
770
775
780
785
790
795
800
805
810
815
820
825
830
835
840
845
850
855
860
865
870
875
880
885
890
895
900
905
910
915
920
925
930
935
940
945
950
955
960
965
970
975
980
985
990
995



Alternatively, at least one of the anchors may be positioned anywhere past the ostium and within the fallopian tube, while the other extends into the uterus, depending on their length and configuration. Preferably, at least some anchoring is provided along the intramural to isthmic region of the fallopian tube. In some embodiments, electro-surgical attachment of an intraluminal device to a surrounding luminal wall may provide effective anchoring even without loops and other anchoring structures. Electrical current may also be used to decouple the intrafallopian device from the delivery system, typically by electrolytically dissolving a solder bond. Current may be also actuate an anchor, such as by releasing a resilient radially expandable tubular structure within the fallopian tube.

2556

15566



BRIEF DESCRIPTION OF THE DRAWINGS

A preferred form of the present invention will now be described by way of example with reference to the accompanying drawings, wherein:

Fig. 1 illustrates a first embodiment of a contraceptive intrafallopian device according to the present invention.

Fig. 2 illustrates a primary coil used in the contraceptive intrafallopian device of Fig. 1.

2556 16620



Fig. 3 illustrates a secondary coil which has been imposed on a primary coil as used in the contraceptive intrafallopian device of Fig. 1.

Fig. 4 illustrates a corewire for used with the contraceptive intrafallopian device
5 of Fig. 1.

Fig. 5 is a cross-sectional view of a contraceptive delivery system having the contraceptive intrafallopian device of Fig. 1.



Fig. 6 illustrates an alternative embodiment of the present contraceptive intrafallopian device.

Fig. 7 illustrates a primary coil used in the contraceptive intrafallopian device of Fig. 6.

5 Fig. 8 schematically illustrates a contraceptive delivery system including the contraceptive intrafallopian device of Fig. 6.

10 Figs. 9 and 10 illustrates a method of delivery of a contraceptive intrafallopian device according to the present invention.

Figs. 11A-D illustrate intrafallopian contraceptive devices having straight primary coils, together with associated delivery devices and systems.

15 Figs. 12A-E illustrate a variety of intrafallopian contraceptive devices which are adapted to promote a tissue reaction that enhances the contraceptive efficacy of the device.

20 Fig. 13 illustrates a method for introducing a dense braid of fiber material into a helical coil of a contraceptive device.

Figs. 14-14E illustrate helical coils which adapt to varying tubal sizes to enhance retention of the contraceptive device within the fallopian tube.

25 Fig. 15A-D illustrate cross-sectional views through the fallopian tube before, during, and after delivery of a contraceptive device having a radially expandable helical coil, and also illustrates the enhanced efficacy provided by tissue reactions such as tissue ingrowth into and around the helical coil.

30 Fig. 15E illustrates the self-guiding capabilities of a contraceptive device having a straight primary coil.

Fig. 16 illustrates a contraceptive delivery system having a detachable distal corewire.

35 Fig. 17 schematically illustrates a kit including a contraceptive delivery system and instructions for its use.

Figs. 18A-C schematically illustrate alternative tubular radially expandable retention structures which can

mechanically anchor a contraceptive device in the fallopian tube.

5 Figs. 19A and B illustrate an intrafallopian contraceptive system in which a hand-held battery electrically actuates the retention structure by transmitting a current which heats a shape-memory alloy of the retention structure.

Figs. 20A and B illustrate an intrafallopian contraceptive device and method for its use to support a coil comprising copper within the utero-tubal junction.

10 Figs. 21A-C illustrate alternative structures comprising copper and methods for their use to inhibit conception, according to the principles of the present invention.

15 DETAILED DESCRIPTION OF THE SPECIFIC EMBODIMENT

The present invention encompasses a contraceptive intrafallopian device which can alternatively be used as both a permanent and a reversible means of contraception. The present contraceptive methods and devices minimize the danger of non-use which has limited the efficacy of prior art contraceptive techniques. Moreover, the location of the present devices within the fallopian tubes provides a reduced risk of the infectious complications, increased bleeding, and pelvic pain associated with intrauterine devices (IUDs). The location and the novel shape of the present intrafallopian device provides significant advantages over IUDs, which have been found to be susceptible to unplanned expulsion and removal due to excessive pain and bleeding. The present invention takes advantage of the increase in effectiveness associated with copper IUDs, providing a resilient structure including copper which may be transcervically positioned without the need for surgery.

Although the present contraceptive method is included within a group of contraceptive techniques generally referred to as fallopian tube occlusion methods, the present invention does not necessarily rely solely on blocking the fallopian tube to prevent fertilization. Instead, contraception is apparently provided by disrupting of ovum

transport, the process of fertilization, and/or cleavage of the ovum. While the effect that copper has on these processes is not fully understood, it does appear that copper intrafallopian devices offer potentially significant increases in effectiveness over intrafallopian devices formed of other materials. Contraception may alternatively be provided or enhanced by a spermicidal agent attached to the device. Optionally, the present invention further encompasses devices which promote the growth of tissue within the tube to induce tubal occlusion, further inhibiting conception. In some embodiments, polyester fibers such as Dacron®, Rayon®, or the like, are bonded to the surface of the coil using a polymeric adhesive. The polyester fibers promote increased tissue growth around the coil, thus further reducing the possibility of expulsion of the device from the fallopian tube.

Conveniently, the present resilient structures are adapted to be releasably affixed over a corewire, the corewire restraining the resilient structure in a straight configuration. As the resilient structure has an outer diameter when in the straight configuration which is less than the inner diameter of the fallopian tube, the catheter containing the present intrafallopian device is easily transcervically introduced.

The present invention may be anchored within the isthmus of the fallopian tube, overcoming the unintended expulsion of the device and the resulting failure of the contraceptive method. Such intrafallopian device expulsion has been the single greatest factor limiting the efficacy of easily positioned intrafallopian contraceptive techniques. The present intrafallopian devices are generally elongate resilient structures pre-formed into secondary shapes. These secondary shapes will preferably form anchors proximally and distally of the narrowest portion of the fallopian tube, called the isthmus. The secondary shape preferably has a larger outer diameter than the inner diameter of the isthmus. Anchoring may also be possible with a structure spanning other portions of the tubal lumen, often between the ostial opening and the isthmus.

The present device is generally readily removed by snaring the resilient structure near the proximal end and pulling proximally on the resilient structure, thereby straightening the resilient structure and allowing it to be withdrawn without injuring the fallopian tube. Alternatively, an electrical current is applied to the device after it is positioned within the fallopian tube, providing permanent sterilization. Electrical current might also effect detachment of the device from the delivery system using a system similar to that described in U.S. Patent No. 5,624,449, the full disclosure of which is incorporated herein by reference. *In situ* actuation of an anchor might be effected by releasing a resilient structure to expand *in situ* with a similar mechanism, or by a current induced phase change of a shape memory alloy (for example, causing a straight Nitinol® ribbon to curl within the fallopian tube with a current).

Referring now to Fig. 1, a first embodiment of the present contraceptive intrafallopian device 10 is formed from a resilient primary coil 12. Primary coil 12 has a proximal end 14 and a distal end 16, the latter having an atraumatic endcap 18. Primary coil 12 further includes three portions: a proximal anchor portion 20, a distal anchor portion 22, and a lumen-traversing region 24. Proximal and distal anchors 20,22 are biased to form anchoring loops 26, as described hereinbelow.

Lumen-traversing region 24 comprises a substantially straight portion of primary coil 12. A ribbon 28 is wound over the outer surface of primary coil 12 to provide a helical shape. Ribbon 28 includes sharp outer edges 29, which firmly anchor lumen-traversing region 24 in the fallopian tube wall when torque is applied to intrafallopian device 10. The ribbon is preferably formed of a high strength biocompatible metal, ideally being stainless steel. The ribbon is attached to primary coil 12 at a proximal joint 30 and a distal joint 32, which may be formed of solder, heat-shrink tubing, or the like.

Referring now to Fig. 2, primary coil 12 is most easily formed in a straight configuration as a cylindrical

coil or spring, preferably having an outer diameter in the range from 0.005 inch to 0.05 inch, and having a length in the range from 20 mm to 150 mm. Ideally, primary coil 12 has an outer diameter in the range from 0.01 inch to 0.05 inch and a length in the range from 30 mm to 125 mm.

Preferably, primary coil 12 is formed from a beryllium copper alloy wire. Beryllium copper provides the resilience necessary to avoid expulsion of the device, and also provides the increased effectiveness of a copper contraceptive intrafallopian device. Such a beryllium copper wire will typically have a diameter from 0.002 inch to 0.01 inch. To provide the increased efficacy of a copper intrafallopian device, primary coil 12 preferably comprises an alloy including 75% copper. Alternatively, primary coil 12 is formed from a resilient metal, such as stainless steel, platinum, a shape memory alloy, or the like. If such materials are used, primary coil 12 is preferably plated with copper or a copper alloy or otherwise has copper attached.

Primary coil 12 includes a body winding 42 and a thread winding 44. Body winding 42 is formed with the minimum possible pitch to increase the stiffness of primary coil 12. Thread winding 44 will typically comprise from 0.1 cm to 2.0 cm adjacent to proximal end 14, and will have a pitch roughly twice that of body winding 42.

Referring now to Fig. 3, the proximal and distal anchors are formed by imposing a bent secondary shape on selected portions of primary coil 12. The secondary shape preferably comprises loops 26 formed by bending primary coil 12, and heat treating the primary coil while it is bent. A wide variety of secondary shapes may be used, including sinusoidal curves, alternating loops, or loops separated by straight sections so as to form a "flower coil," as more fully described in co-pending U.S. Patent Application No. 08/474,779, the full disclosure of which is herein incorporated by reference. In most cases, the bent secondary shape will have an outer cross-section 46 which is larger than the fallopian tube to provide effective anchoring.

Referring now to Fig. 4, a corewire 50 for use with intrafallopian device 10 (Fig. 1) comprises a resilient wire 52 which tapers towards a distal end 54. Wire 52 is sufficiently stiff to restrain intrafallopian device 10 in a straight configuration, typically comprising stainless steel, platinum, or the like. A short section of coil forms corewire threads 56 attached at threadjoint 58. Threads 56 match the windings and pitch of threadwindings 44 of primary coil 12.

Referring now to Fig. 5, an intrafallopian contraceptive system 60 comprises corewire 50 inserted within a lumen 62 through intrafallopian device 10. Intrafallopian device 10 is releasably attached by engaging thread windings 44 with threads 56. Thus, intrafallopian device 10 is disengaged by torquing a proximal end of corewire 50 once intrafallopian device 10 is in position.

Referring now to Fig. 6, an alternative embodiment of the present intrafallopian device is again formed from a resilient primary coil 112 having a proximal end 114 and a distal end 116. The former includes a friction fitting 115. Primary coil 112 again includes three portions: a proximal anchor portion 120, a distal anchor portion 122, and a lumen-traversing region 124. Proximal and distal anchors 120, 122 are here biased to form opposed anchoring loops 26, thereby increasing the relaxed overall cross-section of the proximal and distal anchors. A ribbon 128 is wound over the outer surface of primary coil 112 to provide a helical shape, as described above.

Referring now to Fig. 7, primary coil 112 comprises a uniform body winding 142. The secondary shape is imposed on the straight cylindrical coil as opposed loops 126, or alternatively as multiple loops of a flower coil.

Referring now to Fig. 8, an intrafallopian contraceptive system using alternative intrafallopian device 100 includes a corewire 152 which tapers towards a distal end 154. Friction fitting 115 fittingly engages corewire 152, which restrains primary coil 112 in a straight configuration. A release catheter 164 is slidably disposed over corewire 152 proximally of alternative intrafallopian device 100, allowing

the device to be released by withdrawing corewire 152 relative to the release catheter.

Use of the present contraceptive intrafallopian device will be described with reference to Figs. 9 and 10. A
5 uterine introducer cannula 70 is inserted transcervically through a uterus 72 to the region of an ostium 74. Alternatively, a hysteroscope may be used in place of cannula 70, or an echogenic and/or radiopaque device might be placed under sonographic or radiopaque guidance.

10 Intrafallopian contraceptive system 60 is advanced distally of introducer cannula 70 and maneuvered through the fallopian tube, preferably until intrafallopian device 10 extends distally of the isthmus. Optionally, intrafallopian contraceptive system 60 is self-guided, with corewire 52 bent
15 near distal end 54 to assist intraluminal maneuvering. Alternatively, a guide wire and catheter are advanced into the fallopian tube first, and the guide wire is replaced with intrafallopian contraceptive system 60. In either case, the intrafallopian device will generally be axially positioned
20 with lumen-traversing region 24 within a target region 84 adjacent to isthmus 80. Preferably, at least one loop of distal anchor 22 is distal of target region 84, and at least one loop of proximal anchor 20 is proximal of target region 84 to form the distal and proximal anchor bends.

25 Once intrafallopian device 10 is properly positioned, corewire 50 is torqued to set ribbon 28 in the tubal wall. The corewire may then be unthreaded from intrafallopian device 10 by rotating the corewire in the opposite direction, disengaging threads 56 from thread
30 windings 44. The corewire is then free to slide proximally, releasing the primary coil. As the distal end of the primary coil is released, a distal anchor bend 90 is formed. Similarly, a proximal loop forms a proximal anchor bend 92. The anchor bends help to axially restrain the device within
35 the fallopian tube, and also prevent rotation around the helical shape of lumen-traversing region 24. As seen in Fig. 10, the loops need not assume their relaxed form to provide effective distal or proximal anchors.

The present invention further encompasses permanent sterilization by passing a current through the corewire to the intrafallopian device prior to withdrawing the corewire. Fallopian tube tissue in contact with the intrafallopian device is desiccated, and thus attached to the present intrafallopian device. This action also causes permanent tubal damage, leading to the formation of scar tissue which encapsulates the intrafallopian device and causes permanent occlusion of the tubal lumen. Clearly, the corewire/primary coil interface must be conductive to allow the present non-surgical method of permanent sterilization.

The intrafallopian contraceptive methods and devices of the present invention can provide highly effective contraception even when the contraceptive device does not totally occlude the lumen of the fallopian tube. To minimize distention of the delicate tubal tissue, the present invention will often leave some open lumen within the fallopian tube, at least when initially deployed. In fact, these contraceptive devices will often comprise perforate tubular structures having lumens. Nonetheless, contraception can be provided by disrupting the normal architecture and/or function of the fallopian tube, despite the presence of an open lumen. This concept is referred to herein as "functional occlusion". As used herein, a device which provides functional occlusion means that the device, when implanted in the fallopian tube, disrupts the normal architecture and/or functioning of the fallopian tube so as to inhibit fertilization and/or conception.

The size of an occlusive device required to provide functional occlusion may depend on the material of the device, the position the device is to be deployed within the fallopian tube, the interaction between the device and the surrounding tubal wall, and the like. For example, intrafallopian contraceptive structures which include fibers of polyester may incite ingrowth of the tubal tissues into the device. As a result of this tissue/device interaction, a relatively small device which promotes ingrowth may be capable of providing effective occlusion. In fact, such a device may be capable of

providing total occlusion by inciting sufficient ingrowth so that the hyperplastic tubal walls, in combination with the device, block all passage through the tubal lumen. Hence, relatively small, easily inserted structures may effectively inhibit conception without the danger of distending the tubal wall.

One easily inserted intrafallopian contraceptive structure which may be capable of providing effective tubal occlusion is illustrated in Fig. 11A. A straight contraceptive device 200 includes a straight primary coil 202 around which is disposed a secondary helical coil 204 as described above. Secondary coil 204 is affixed to primary coil 202 at a pair of bonds 206. As illustrated above in Fig. 6, the secondary helical coil may have an inner surface which is larger than the outer surface of primary coil 202, which may facilitate embedding the corners of the secondary coil in the surrounding tubular wall. However, unlike the intrafallopian devices described hereinabove, straight device 200 remains substantially straight between a proximal end 208 and a distal end 210 when the primary coil is at rest.

Primary coil 202 will typically be formed from wire having a diameter of between about 0.002 and 0.009 inches, by winding the wire to form a coil having a diameter between about 0.010 and 0.040 inches. Primary coil 202 will often have a length of between 2.9 and 3.5 cm. The ribbon used to form secondary helical coil 204 will generally have a width between about 0.005 and 0.020 inches, and a thickness of between about 0.0005 and 0.005 inches.

In the exemplary embodiment, straight device 200 includes a primary coil 202 having a total length of between about 3.0 and 3.35 cm. The exemplary primary coil 202 is wound from platinum wire, the platinum wire having a thickness of 0.005 inches, which is wound to provide a primary coil having an outer diameter of about 0.018 inches and a length of about 3.0 cm. Secondary coil 204 is formed from a platinum ribbon having a width of 0.012 inches and a thickness of 0.002 inches. Bonds 206 comprise gold solder and secondary coil 204 has a length of about 0.5 to 1.0 cm and an outer diameter of

between about 0.035 to 0.040 inches when affixed to the primary coil 202. Solder is also used to form an atraumatic tip at distal end 210.

Referring now to Figs. 11B and 11C, a self-guiding
5 contraceptive delivery system 212 includes straight
contraceptive device 200 and a flexible tip corewire 214. As
described above, threads 216 on flexible tip corewire 214 mate
with the proximal end 208 of straight contraceptive device
200, the threads ideally comprising a stainless steel coil
10 having approximately the same dimensions as primary coil 202
and affixed to the corewire with yet another gold solder joint
206.

Advantageously, distal end 218 of corewire 214 need
not have sufficient stiffness and strength to restrain a coil
15 biased to form a bent secondary shape. As a result, the
thickness of corewire 214 may be optimized to enhance the
trackability and pushability of self-guided contraceptive
system 212, thereby enhancing the ability of the contraceptive
system to act as its own guidewire.

20 Delivery of the contraceptive device is facilitated
by using a corewire having a relatively long, stiff proximal
section and a relatively short, flexible section, the flexible
section typically being tapered as illustrated. The thickness
and material properties of these sections are selected to
25 provide enough column strength to allow corewire 214 to
advance straight device 200 within the fallopian tube, but
enough flexibility at the distal end of the delivery system
for distal end 210 to navigate the tortuous fallopian tube. A
relatively thick proximal section also improves the torque
30 transmission capabilities of the wire, particularly for
torquing and embedding the outer coil against the tubal wall.

Proximal section 220 of corewire 214 will preferably
be flexible enough for delivery through a flexible catheter
and/or through the working channel of an endoscope. The
35 corewire will generally comprise a material which resists
kinking and resiliently returns to its original shape, ideally
comprising a shape memory alloy such as Nitinol® or a treated
stainless steel. Such resilience may be tailored to enhance

the ability of the delivery system to access the tubal ostium and advance the contraceptive device into the fallopian tube. In some embodiments, corewire 214 will be capable of transmitting heat, electrical current, and/or some other energy which induces scarring, electrocautery, or the like, so as to attach the contraceptive device within the fallopian tube. Alternatively, the transmitted energy may decouple the device from the corewire, for example, by melting a coupler.

In a particularly advantageous aspect, threads 216 of delivery system 200 may be adapted to enhance visualization of the detachment process. For example, a first portion of the threads 222 may be a first color (such as green) while a second portion of the threads 224 may be a second color which contrasts sharply with the first color (such as red). As they are near the proximal end of the device, threads 216 will often be more visible than the remainder of the contraceptive device. The threads may even protrude through the tubal os into the uterus for viewing through the hysteroscope. By visually monitoring highly contrasting colors of the thread portions through the hysteroscope, the attending physician will be provided with direct feedback on the decoupling process. The thread portions may be colored by coating, anodizing, oxidation, polishing, the use of differing materials, or the like. A stripe or other mark may also be provided on the delivery wire to help monitor rotation. Alternative embodiments may use threads having high contrast under imaging.

Still further capabilities may be incorporated into the delivery system. For example, a "smart" delivery device may be able to sense its position within the fallopian tube magnetically, electrically, optically, ultrasonically, or the like. Similarly, the deployed device may incorporate structures which allow the physician to remotely verify the position and presence of the device without having to access the fallopian tube (e.g., using a magnetic sensor, impedance, and/or radio activity).

In the exemplary embodiment, corewire 214 comprises a shape memory alloy such as Nitinol®. Proximal portion 220

of corewire 214 has a thickness of between about 0.018 and 0.040 inches, ideally being about 0.035 cm, and the corewire tapers over a length of about 5.0 cm to a minimum thickness of between about 0.002 and 0.008 inches, typically about 0.003 inches at distal end 218.

One method for attaching polyester fibers 226 to straight contraceptive device 200 is illustrated in Fig. 11D. As described above, such polyester fibers promote tissue ingrowth, which can help affix the device within the fallopian tube. Additionally, such tissue ingrowth may also help to further occlude the lumen of the fallopian tube. Fibers 226 are shown tied in loops around the secondary coil, ideally using between about 5 and 7 loops and fiber.

A wide variety of alternative mechanisms may be employed to incite a tissue reaction which enhances the functional occlusion of the intrafallopian contraceptive device. For example, materials such as collagen, hydroxyapatite, solid or fibrous PTFE, or the like may be used. Biodegradable coatings may cause tissue ingrowth or scarring, and then degrade to leave a fully or partially occluded lumen. In some embodiments, the engagement between outer coil 204 and the tubal wall injures the epithelial tissues, and the healing process results in the formation of scar tissues which interfere with the functioning of the fallopian tube.

A variety of alternative ingrowth promoting intrafallopian contraceptive devices are illustrated in Figs. 12A-E. Generally, each of these devices includes some element which promotes ingrowth of tubal tissues therein. A porous secondary coil 230 may be formed of a porous metal, ideally comprising a micro-porous shape memory alloy such as Nitinol®. In some embodiments, ingrowth bonds 232 may be formed of, or coated with, a material such as bioglass, ceramics, or the like so as to promote tissue ingrowth, so that the entire device may promote ingrowth. Surface treatments may also encourage ingrowth. For example, blasting a surface with small particulates can create a somewhat divoted and porous texture. Such porous textures at the surface, with micron-

sized pores, may produce the desired tissue reaction. Alternative embodiments may include an open cell ingrowth promoting structure, such as the open cell foams used to attach some breast implants.

5 In some embodiments, discrete bodies 234 may be formed as rings or annular beads using any of the above listed tissue ingrowth materials, coatings, or treatments. Wound, wrapped, or braided fiber material 236 may also be disposed between the primary and secondary coils, the fiber material
10 typically comprising a polyester such as Dacron®, Vicril®, or the like. Dense fiber materials within the device may enhance the reaction and/or ingrowth of the surrounding tubal tissues, and also decreases the amount of open space within the device, thereby minimizing any prosthetic lumen. Fiber material 236
15 may also be in the form of a thick felt, or may simply be spun with several layers of windings.

Still further alternative ingrowth promoting elements are possible, such as tubular fabric 238 of felt, braided or woven material, or the like. Tubular fabric 238
20 provides an open conduit at the proximal end of the device to avoid impeding with the removal of the corewire, and the outer diameter of the tubular fabric will preferably be less than the outer diameter of the secondary coil. In some embodiments, simply providing an internal fabric 240 in the
25 form of a textile mesh or felt inside the primary coil may be sufficient to incite ingrowth of the tubal tissues into the coil, affixing the coil in place and providing functional occlusion of the fallopian tube.

Referring now to Fig. 13, a particularly
30 advantageous method for producing a contraceptive device having a dense fiber braid 250 is illustrated. Dense fiber braid 250 is initially formed by wrapping several layers of fiber around a mandrel. After about fifteen layers of fiber have been wrapped over the mandrel, the wound fiber is slid
35 off the mandrel, and the windings are processed to form the braid. The braid is affixed to contraceptive device 200 adjacent one of the bonds, and the fiber braid is then wound between the windings of secondary coil 204. As a result, at

least a portion of fiber tube 250 is disposed in the annular space between the primary coil and secondary coil 204. Often times, some portion of the fiber will also extend radially beyond secondary coil 204, as illustrated.

5 The use of dense fiber braid 250 provides a much greater amount of fiber and a more radially compact, easily deployable assembly than a structure which includes loops tied radially around the secondary coil. Such densely packed fiber thereby makes use of an otherwise open space, and the enhanced
10 amount of fiber should provoke a more robust tissue reaction. Specifically, dense fiber braid 250 will have a smaller pore size, which is generally advantageous for tissue ingrowth. This combination of an enhanced tissue reaction, with a less axially open design, would appear to provide significant
15 advantages for functional occlusion of the fallopian tube.

A still further alternative intrafallopian contraceptive device 200' is illustrated in Fig. 14. Alternative device 200' includes several of the same primary structures described hereinabove regarding straight
20 contraceptive device 200, but makes use of a fiber tube 252 to provide the advantages of high fiber density and a small radial package. In this embodiment, the fiber is again wrapped around a mandrel several times (ideally about 15 times) and then removed as a fiber tube. Tube 252 is slid off
25 the mandrel and onto the primary coil. The tube may be positioned before or after secondary coil 204 is attached at bond 206, and will generally occupy the annular space between the primary and secondary coils. The ends of tube 252 can be tied to keep the tube in position during delivery.

30 Alternative contraceptive device 200' also differs from the previous structures in that secondary coil 204 has a free end 254 which is not affixed to primary coil 202. As free end 254 can move relative to primary coil 200, secondary coil 204 can expand radially well beyond bond 206, and can
35 also be radially compressed to provide a very small outer diameter during delivery of the device. Hence, the diameter of secondary coil 204 in alternative device 200' provides a highly radially variable tubular structure which can easily

adapt to a wide variety of tubal lumen cross-sectional sizes to retain the contraceptive device within the fallopian tube.

A highly radially expandable tubular retention structure has several significant advantages. First, the structure can be inserted in a narrow profile configuration and radially expanded within the fallopian tube to provide a secure anchor with minimal danger of protruding through the delicate tubal wall. Additionally, the stiffness of the helical secondary coil can be tailored to provide the appropriate engagement force and/or damage to the wall tissue so as to provoke the desired tissue reaction, whether it be scar tissue formation, ingrowth, or the like. Torquing of a free ended helical coil may also be used to adjust the outer diameter during delivery.

The enhanced variability in outer diameter provided by an outer coil 204 having a free end 254 can be understood with reference to Figs. 14A-C. Generally, outer coil 204 will here have an outer diameter of over about 0.080 mm in its relaxed state, the outer diameter of the secondary coil preferably being biased to form a helix with an outer diameter of about 1.0 mm when at rest, and will ideally be compressible to an outer diameter of 0.1 mm for insertion. Outer coil 204 of alternative device 200' may be easily radially compressed by drawing free end 254 proximally away from bond 206, by wrapping the free end around primary coil 202, or by some combination of both.

As illustrated in Figs. 14B and C, the device may be restrained in a small diameter configuration by a delivery catheter 256, by articulatable jaws 258, or the like. Regardless, secondary coil 204 will generally be restrained until the device is positioned within the fallopian tube, and will then be released *in situ* by axially withdrawing catheter 256, articulating jaws 258, or the like. Still further alternative *in situ* release mechanisms are possible, such as dissolving or dissipating a crystal or electrolytic coating which radially restrains the secondary coil, a phase change in a shape memory alloy, or the like, as described above. It should be noted that the free ended secondary coil is

illustrated in Figs. 14A-C without the optional dense fiber tube of Fig. 14A for clarity. Nonetheless, the enhanced radial variability provided by a free ended helical coil (or by other perforate tubular structures) may be either used
5 alone or combined with other tissue reaction structures described hereinabove to provide functional occlusion and contraception.

Alternative helical retention structures are illustrated in Figs. 14D and 14E. A tapered coil 203 may be
10 advanced distally, either axially or by rotationally threading the device, to embed the structure into a tapering portion of the tubal wall. The device can accommodate a variety of tubal sizes, as it need only be advanced until proper engagement has been achieved. Variable stiffness along the outer coil may be
15 provided by a coil formed with a tapering ribbon 207, or the like.

Alternative structures for releasably restraining secondary coil 204 are illustrated in Figs. 14F-H. In the embodiments of Figs. 14F and G, corewire 152 is rotationally
20 coupled to primary coil 202, and hence to the distal portion of secondary coil 204 by bond 206 (see Fig. 14C). A tab 259 is affixed to a proximal end of secondary coil 204, the tab preferably protruding radially inwardly from the coil, the tab ideally comprising a small diameter annulus or collar having
25 an axis parallel to the secondary coil axis. Tab 259 is releasably received by a keyhole slot 257 in delivery catheter 256. The tab is axially restrained in the slot when the tab engages one side of the slot, but is free to slide axially from the slot when rotationally disengaged or pressed against
30 the other side.

Prior to delivery, secondary coil 204 is restrained in a small diameter configuration by engagement between tab 259 and slot 257. Secondary coil 204 is tightly wound down, so that the secondary coil biases the tab toward the
35 restrained position. The proximal portions of the corewire and delivery catheter can be rotationally affixed to each other (ideally by a Tohey-Borst valve) to restrain the device in the small configuration. This may also prevent distal

movement of the contraceptive device from the catheter and corewire.

Once the device is positioned, allowing the proximal portions of the corewire and catheter to rotate relative to each other (by releasing the Tohey-Borst valve or the like), and/or actively rotating one of these structures, can unwind the secondary coil and allow tab 259 to slide axially free of the catheter. Optionally, as shown in Fig. 14G, an alternative keyhole slot 263 having an angled or radiused proximal surface may be used to urge tab 259 toward a release portion 261 of the slot by pushing the surface distally against the tab.

Still further release mechanisms are possible, including the system illustrated in Fig. 14H. A proximally inwardly tapering body or brake 265 is affixed to primary coil 202, and is fittingly received by a tapering receptacle at the distal end of delivery catheter 267 when a proximal portion of secondary coil 204 is disposed therebetween. Secondary coil 204 may optionally be held in its wound-down configuration at the proximal end of the delivery system by a Tohey-Borst valve, and can be released to unwind by moving the catheter proximally relative to corewire 152 (and hence primary coil 202 and body 265), and/or by releasing the Tohey-Borst valve.

The use of a tubular, radially expandable intrafallopian device, and also the significance of tissue reaction in providing functional occlusion, can be further understood with reference to Figs. 15A-D. A lumen L of a fallopian tube F is largely a potential space, much like a deflated balloon. Tubal wall W can expand around structures which are inserted into lumen L, such as around catheter 256 which radially restrains a free ended secondary coil 204. Hence, the size of the irregular luminal cross-section may be measured by the diameter of a device it can accommodate.

Work in connection with the present invention has found that fallopian tubes can vary significantly in inner lumen cross-sectional sizes. The maximum diameter of a device which a fallopian tube can accommodate at its smallest point can range anywhere from 0.2 to 1.5 mm. For devices having a

fixed cross-section, relatively large diameters will make the device more difficult to deliver. However, if the device is made too small, it can be more easily ejected from the fallopian tube. While fixed cross-sectional devices may still be effective (for example, by providing a range of different device sizes), the use of a radially expandable tubular structure such as free ended helical coil 204 allows the device to compensate for the substantially anatomical differences between users.

As generally described above, catheter 256 may optionally be positioned by first accessing the fallopian tube with a guidewire, and then advancing the catheter over the positioned guidewire. Alternatively, the catheter and contraceptive device may be advanced distally using the distal end of the primary coil as a guidewire. Regardless, once the contraceptive device is positioned at the desired axial location (generally from adjacent the isthmus to the intraluminal region, but optionally anywhere from the cornual area to adjacent the distal fimbria), catheter 256 is withdrawn proximally while restraining the contraceptive device axially with the proximal end of corewire 214. As catheter 256 is withdrawn, secondary coil 204 expands radially and engages the surrounding tubal wall W, as illustrated in Fig. 15C. Secondary coil 204 may optionally be torqued against the surrounding tubal wall from the proximal end of corewire 214, after which the corewire is unthreaded from the contraceptive device and removed.

Although the tissues of the tubal wall protrude between the windings of secondary coil 204, a significant portion of lumen L remains open. Nonetheless, functional occlusion is provided so long as the deployed device adequately interferes with fertilization so as to inhibit conception. Functional occlusion may be enhanced by the formation of scar tissues and the growth of tissues from the tubal wall so as to occlude lumen L (ideally both inside and outside of the tubular retention structure), as illustrated in Fig. 15D. Such scar tissue formation will also aid in anchoring the device.

As can be understood with reference to Fig. 15D and Fig. 16, open areas within the contraceptive device along the axis of fallopian tube F can present some risk of providing a passageway for fertilization. To avoid providing a prosthetic lumen defined by the inner surface of primary coil 202 after corewire 214 is removed, a detachable delivery wire 260 is formed in two pieces. Distal delivery wire 264 is coupled to proximal delivery wire 262 by a threaded fastener 266. Fastener 266 provides column strength to the detachable delivery wire. This allows the distal portion of the delivery wire to remain within the primary coil when the contraceptive device is detached. Clearly, a wide variety of coupling mechanisms might be used. Advantageously, a threaded coupler allows the device to be torqued in one direction and detached by rotating the proximal delivery wire 262 in the other direction, generally as described above.

The use of primary coil 202 (in combination with corewire 214) as a guidewire can be understood with reference to Fig. 15E. The good proximal column strength of the corewire and the distally increasing flexibility of the combined corewire and primary coil at the distal end of the delivery device greatly facilitates axially advancing the device within fallopian tube F. The ability of the corewire 214 to transmit torque can also help advance the delivery system distally, as well as allowing the user to embed secondary coil 204 into the surrounding tubal wall. As can also be understood with reference to Fig. 15E, the use of a straight primary coil in a portion of the fallopian tube having significant axial curvature results in resilient engagement of the coil against the tubal wall, and can thereby provide anchoring similar to that described above for pre-bent coils in straight lumens.

Referring now to Fig. 17, a kit 300 includes contraceptive system 212 (in which straight contraceptive device 200 is mounted on corewire 214) within a sterile package 302. Also included in kit 300 are instructions 304, the sterile package and instructions being disposed in packaging 306. The instructions may set forth any of the

method steps for using a contraceptive system as described hereinabove. Delivery system 212 may be protected by a protective sheath 308, and other system components described hereinabove may also be included. Also visible in Fig. 17 is the proximal torquable handle 310 of the delivery system.

Instructions 304 will often comprise printed material, and may be found in whole or in-part on packaging 306 or sterile packaging 302. Alternatively, instructions 304 may be in the form of a recording disk or other computer readable data, a video tape, a sound recording, or the like.

Alternative radially expandable retention structures are illustrated in Figs. 18A through C. A slotted tube retention structure 320 can shorten and expand within the fallopian tube. In general, such expansion may be the result of external forces (such as actuation of a two part delivery system 322), or the retention structure may self-expand when released *in situ*. Forcibly expanded retention structures may have a latching mechanism which prevents collapse when the device is detached from the delivery system in the fallopian tube, and such detachment may be effected by any of the mechanisms described hereinabove.

Still further alternative retention structures may be used in place of helical secondary coil 204 and slotted tube 320. For example, a Malecott retention structure 324 or a braided filament retention structure 326 might be expanded to engage a surrounding tubal wall. In some cases, tubal anchoring may be enhanced by including two or more retention structures, or by providing small barbs which extend axially and/or radially from the expanded retention structure to prevent axial migration. Preferably, such barbs would be too short to perforate through the tubal wall. A wide variety of alternative radially expansible structures which might be adapted for use as a retaining structure in the present intrafallopian contraceptive device are described with reference to vascular stents.

An intrafallopian device having a retaining structure comprising a shape memory alloy is illustrated in Figs. 19A and B. In general, the system applies energy to the

contraceptive device so that the device expands from a low profile (for delivery) to a deployed profile so as to hold the device in place. The device may be heated by transmitting current along two electrically isolated conductors to primary coil 202. Corewire 152 here has an insulating layer 271 and is coupled to a first portion of the coil, while a conductor 269 in delivery catheter 256 is coupled to another portion of the coil. The resistance of the coil to a small current is sufficient to heat and reconfigure the retaining structure. Electrical energy from a common 9-volt hand-held battery within energy source will be sufficient to reconfigure secondary coil 204, which will generally remain in the deployed configuration at body temperature. Alternative energizing systems may use heated saline or the like.

As described above, copper may enhance the efficacy of an intrafallopian contraceptive device 400. As illustrated in Figs. 20A and B, a copper body (for example, in the form of copper coil 402) may extend proximally into and/or through the utero-tubal junction from the fallopian tube. As can be seen in Figs. 21A and C, the copper may alternatively be in the form of copper beads 404, which may be used to form bonds, ingrowth structures, or the like. The copper may be in the form of a plating 406 over a core material 408 for use in the primary coil, secondary coil, or the like.

The release rate of copper is often closely related to the surface area of copper on the device. A total copper surface area over 100mm^2 , and most often in a range from about 300mm^2 to about 400mm^2 will be preferred to provide contraception.

The total volume of copper will affect the duration of the enhanced efficacy the copper provides. To provide lifelong contraception, we should provide sufficient copper for about 25 years (based on the fertility life of a woman). For an exposed copper surface area of 400mm^2 , average copper release rates may be about 25 micrograms per day, based on intrauterine device studies. To allow our intrafallopian contraceptive devices to release copper at this rate for 25 years, we will preferably include at least 0.23 grams or

25.6mm³ of total copper. To provide a reasonable safety factor, a 25-year device may include at least about .34 grams or 38.4mm² of copper volume. These quantities may be provided by each device, or by two devices (in the left and right fallopian tubes) in combination. Similar calculations may be performed for 5-year devices (using the same exposed area and at least 1/5 of the above volume), or to adjust for differing release/areal efficacy resulting from the copper structures being carried in different regions of the fallopian tubes.

In conclusion, the present invention provides a contraceptive intrafallopian device which may be positioned without surgery. While the above is a complete description of the preferred embodiments of the invention, various alternatives, modifications, and equivalents may be used. For example, a wide variety of secondary shapes, including open loops, continuous bends, sinusoidal curves, or the like, may be imposed on the primary coil. Additionally, aspects of these intrafallopian contraceptive devices which are described separately may often be combined (for example, a self-guiding device may also promote ingrowth to affix the device in the fallopian tube). Therefore, the above description should not be taken as limiting the scope of the invention, which is defined instead solely by the appended claims.

The claims defining the invention are as follows:

1. A contraceptive device for use in a fallopian tube having a tubal wall, the contraceptive device comprising:
a tubular retention structure having a proximal end, a distal end, and an axis therebetween and a radially expandable structure disposed about said axis, the retention structure radially expandable in situ from a narrow configuration to an expanded configuration, the retention structure in the narrow configuration having a first diameter suitable for axial insertion into the fallopian tube, and in the expanded configuration having a second diameter larger than the first diameter and adapted to engage the surrounding tubal wall and retain the contraceptive device within the fallopian tube while a portion of the fallopian tube remains open around or through the retention structure.
2. A contraceptive device as claimed in claim 1, further comprising an element disposed along the retention structure, the element adapted to incite a tissue reaction in the tubal tissues adjacent the retention structure so as to inhibit conception, the reaction comprising at least one of: scarring of tubal tissues, ingrowth of the tubal tissues, and sclerosing of the tubal tissues.
3. A contraceptive device as claimed in claim 1, wherein the retention structure comprises a resilient helical coil.
4. A contraceptive device as claimed in claim 3, wherein the coil expands resiliently to safely engage the tubal wall throughout a range of tubal cross-sectional sizes.
5. A contraceptive device as claimed in claim 4, wherein the coil resiliently expands to open diameters throughout the range from about 0.10 to about 1.0 mm with an expansion force sufficient to help retain the contraceptive device in the fallopian tube and insufficient to penetrate through the tubal wall.
6. A contraceptive device as claimed in claim 3, wherein the coil has a sharp outer edge.
7. A contraceptive device as claimed in claim 3, further comprising a conception inhibiting body attached to the coil.
8. A contraceptive device as claimed in claim 7, wherein a portion of the coil is affixed to the body and an end of the coil moves relative to the body when the coil expands from the first diameter.
9. A contraceptive device as claimed in claim 7, wherein the body extends distally of the coil and is resiliently flexible to help guide the contraceptive device distally within the fallopian tube.



10. A contraceptive device as claimed in claim 9, further comprising woven or braided polyester attached to the body.

11. A contraceptive device as claimed in claim 1, wherein at least a portion of the retention structure is straighter than an axial curvature of the fallopian tube, the retention structure being sufficiently flexible to deflect against the tubal wall without
5 injuring the tubal wall, and sufficiently resilient to impose an anchoring force against the tubal wall when the straight portion flexes along the axial curvature of the fallopian tube.

12. A contraceptive device as claimed in claim 11, wherein the retention structure is adapted to resiliently engage the tubal wall with sufficient force to help retain
10 the retention structure in the fallopian tube during ingrowth of tubal wall tissues into an element disposed along the body.

13. A contraceptive device as claimed in claim 11, wherein the retention structure is adapted to penetrate into the tubal wall without perforating through the tubal wall to mechanically retain the body in the fallopian tube.

14. A contraceptive device as claimed in claim 1, wherein the axis is substantially straight when the retention structure is at rest, the retention structure comprising a coil which is axially resilient to facilitate insertion of the retention structure
15 axially into the fallopian tube.

15. A contraceptive device as claimed in claim 1, further comprising an elongate member affixed to the retention structure, the member extending distally of the
20 retention structure and being sufficiently flexible and axially resilient to act as a distal guide wire during distal advancement of the retention structure within the fallopian tube.

16. A contraceptive device as claimed in claim 15, wherein the elongate member comprises a coil and a corewire.

17. A contraceptive device as claimed in claim 16, wherein the corewire is removable from the coil when the coil is disposed in the fallopian tube.

18. A contraceptive device as claimed in claim 1, further comprising an elongate delivery body having a proximal end and a distal end with a first energy conduit extending therebetween, and an energy source coupled to the retention structure by the
30 first conduit so that energy from the energy source reconfigures the expandable structure from a first cross-section to a second cross-section to restrain the retention structure within the fallopian tube.

19. A contraceptive device as claimed in claim 18, further comprising a second conduit extending from the energy source to the retention structure so that



electrical energy is transmitted through at least a portion of the retention structure between the conduits, the conduits comprising conductors.

20. A contraceptive device as claimed in claim 18, wherein the retention structure comprises a shape memory alloy, the energy effecting a phase change in the shape memory alloy to radially expand the expandable structure.

21. A contraceptive method comprising:
transcervically inserting an intrafallopian contraceptive device, having a straight primary coil and a radially expandable structure disposed around said coil, along a fallopian tube by guiding the contraceptive device with a distal guidewire-like structure of the contraceptive device; and

retaining the device, including at least a portion of the guidewire-like structure, within the fallopian tube by expanding said radially expandable structure so that the device inhibits conception.

22. A contraceptive method as claimed in claim 40, further comprising removing a corewire of the guidewire-like structure from within a coil of the guidewire-like device while the device is retained within the fallopian tube and promoting ingrowth of tubal tissues into the contraceptive device.

23. A contraceptive device as claimed in claim 2, wherein the element comprises a braided or woven polyester.

24. A contraceptive device as claimed in claim 2, wherein the element comprises a perforated material defining surface pores which promote tissue ingrowth of the tubal tissues.

25. A contraceptive device as claimed in claim 24, wherein the perforated material comprises a member selected from the group consisting of PTFE, ceramic or microporous polymer.

26. A contraceptive device substantially as hereinbefore described with reference to any one embodiment, as that embodiment is depicted in the accompanying drawings.

27. A contraceptive method substantially as hereinbefore described with reference to any one embodiment, as that embodiment is depicted in the accompanying drawings.

Dated 26 July, 2001

Conceptus, Inc.

Patent Attorneys for the Applicant/Nominated Person

SPRUSON & FERGUSON



1/15

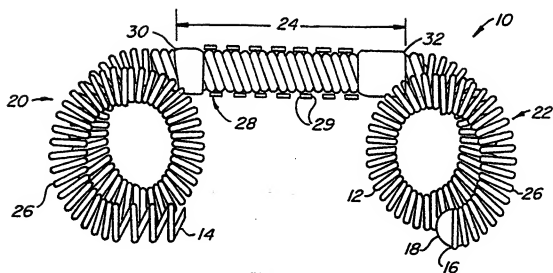


FIG. 1.

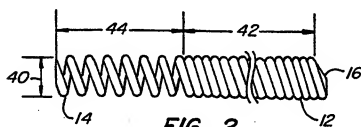


FIG. 2.

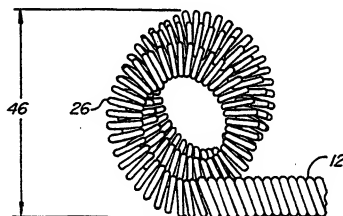
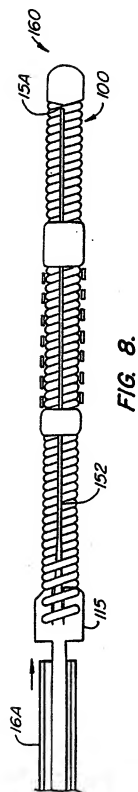
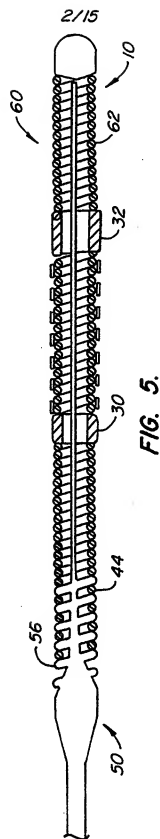
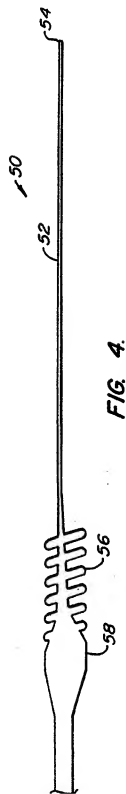


FIG. 3.



3/15

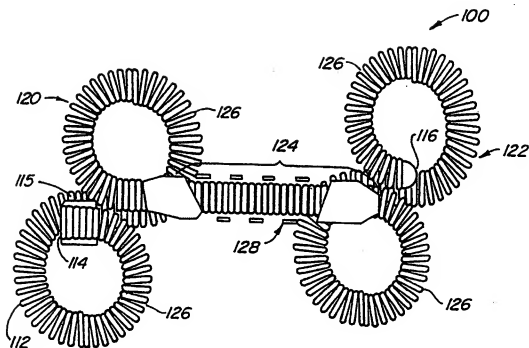


FIG. 6.

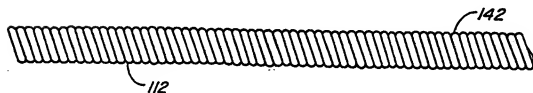


FIG. 7.

4/15

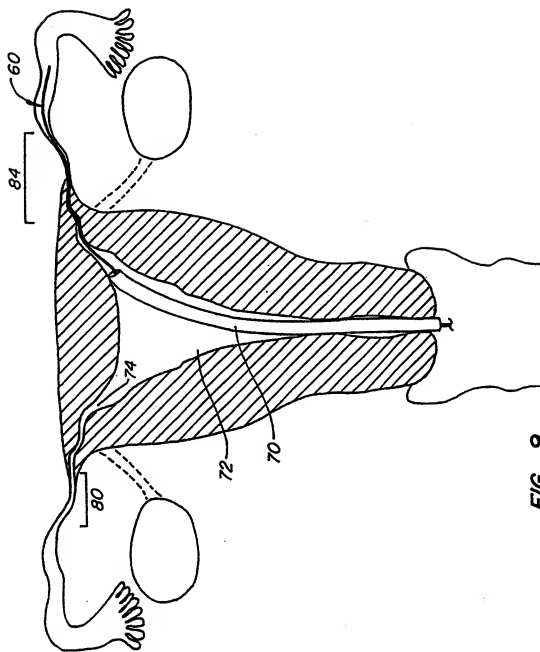


FIG. 9.

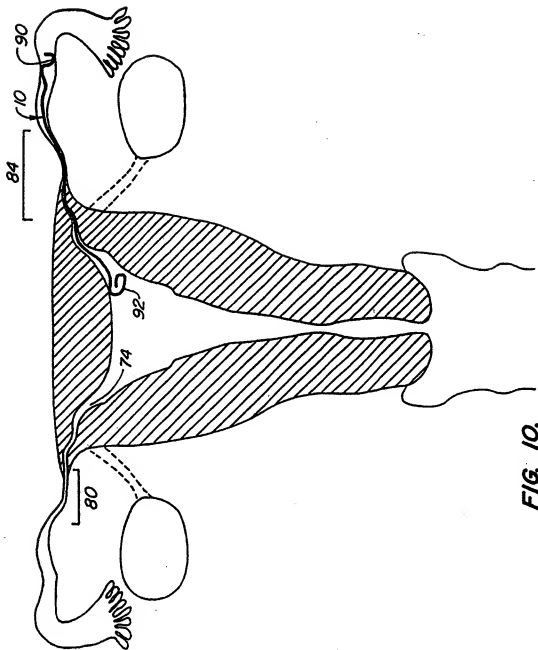


FIG. 10.

6/15

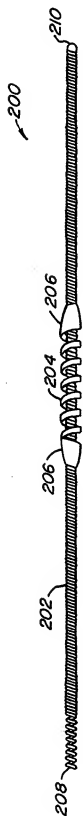


FIG. IIA.



FIG. IIB.



FIG. IIC.



FIG. IID.

7/15



8/15



FIG. 13.



FIG. 14.

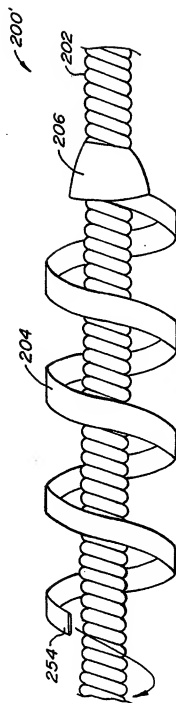


FIG. 14A.

9/15

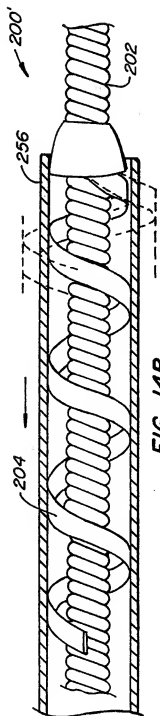


FIG. 14B.

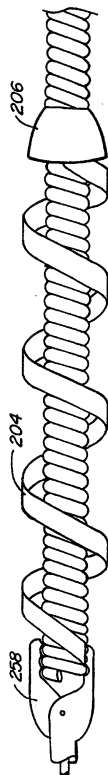


FIG. 14C.

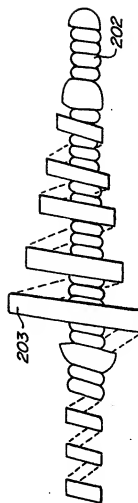


FIG. 14D.

10/15

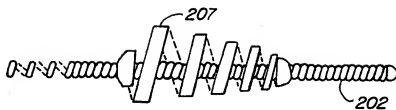


FIG. 14E.

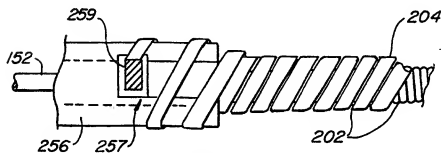


FIG. 14F.

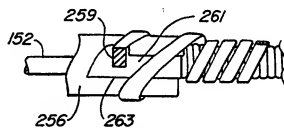


FIG. 14G.

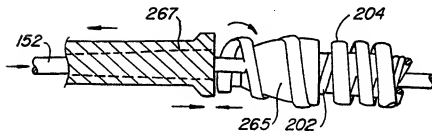


FIG. 14H.

11/15

FIG. 15A.

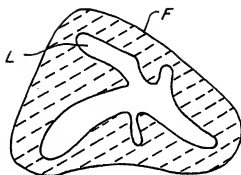


FIG. 15B.

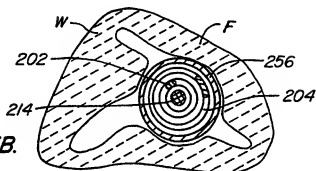


FIG. 15C.

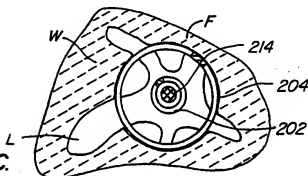
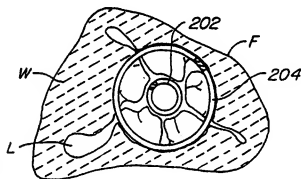


FIG. 15D.



12/15

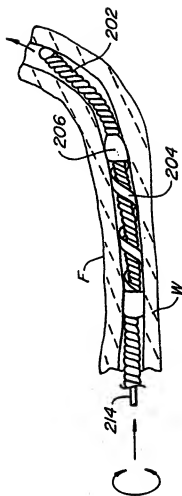


FIG. 15E.

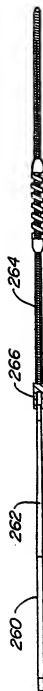


FIG. 16.

13/15

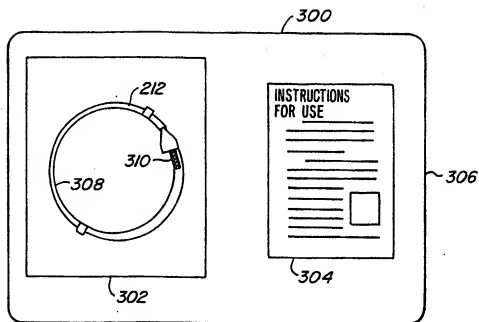


FIG. 17.

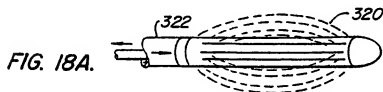


FIG. 18A.

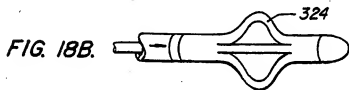


FIG. 18B.

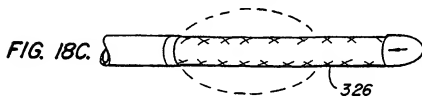
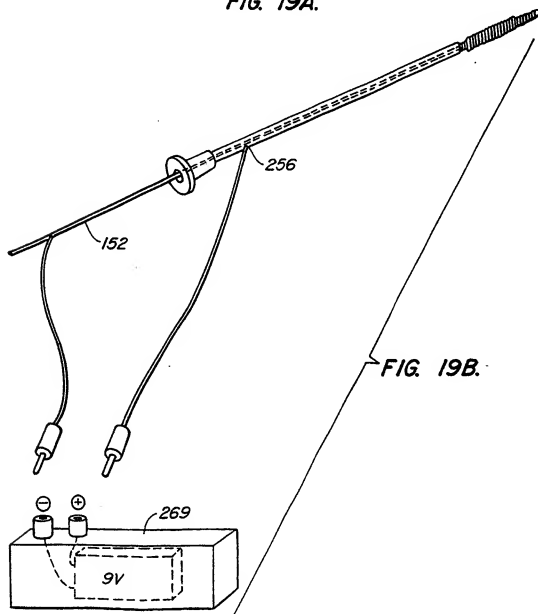
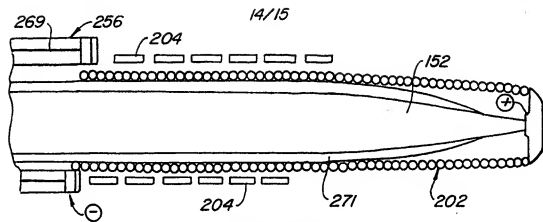


FIG. 18C.



15/15

